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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/509,094

10/22/2004

Abdurrahman Mithat Bozdayi

BJS-2551-158

4496

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EXAMINER

KINSEY, NICOLE

ART UNIT

PAPER NUMBER

1648

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

02/26/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/509,094

Applicant(s)BOZDAYI, ABDURRAHMAN
MITHAT**Examiner**

Nicole E. Kinsey, Ph.D.

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 and 37 is/are pending in the application.
- 4a) Of the above claim(s) 31-35 and 37 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 4, 5 and 7 is/are allowed.
- 6) ☒ Claim(s) 1-3, 8, 9, 11-15, 17-19, 29 and 30 is/are rejected.
- 7) ☒ Claim(s) 6, 10, 16 and 20-28 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/28/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's election without traverse of Group I (claims 1-30) in the reply filed on November 24, 2006 is acknowledged.

Applicant's request to examine claim 37 along with Group I is acknowledged. The previous Examiner did not include claim 37 in the restriction requirement mailed August 23, 2006. Claim 37 is drawn to an oligonucleotide capable of discriminating, in an HBV polynucleotide or fragment thereof, a codon 204 encoding a serine from a codon 204 encoding a methionine, valine or isoleucine in the HBV reverse transcriptase domain. This claim has a different technical feature from that of the claims of Group I. The technical feature of Group I is an isolated HBV polynucleic acid or a fragment thereof that comprises codon 204 encoding a serine. Therefore, because claim 37 has a different technical feature from that of Group I, unity is lacking. Furthermore, the technical feature of Group I does not provide a contribution over the prior art, as evidenced by the teachings of Bozdayi et al. (see art rejection below). Hence, in the absence of a contribution over the prior art, the noted technical feature is not a shared special technical feature. Without a shared special technical feature, the inventions of Group I and claim 37 lack unity with one another. Accordingly, claim 37 is withdrawn from further consideration, and claims 1-30 are currently pending and under examination.

Specification

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: HBV Drug Resistance Methods.

Trademarks

The use of the trademarks has been noted in this application. Trademarks should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks.

Information Disclosure Statement

The information disclosure statement filed September 28, 2004 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because the documents listed under "Other Documents" are not in the proper format (e.g., Author, Title, Date, Pertinent pages, etc.). The documents listed under "Other Documents" have not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement,

including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609.05(a).

Claim Objections

Claim 6 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim must be written in the alternative and must not depend from another multiple dependent claim. See MPEP § 608.01(n). Accordingly, claim 6 has not been further treated on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 8, 9, 11, 12, 15, 19, 29 and 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 8, 9, 11 and 12 recite "HBV variant." It is not clear if applicants intend a variant nucleic acid (or variant protein) or a variant Hepatitis B virus comprising either the nucleic acid of claim 1 or protein of claim 4. If applicants mean a variant nucleic acid or a variant protein, then what mutations or sequence changes, other than a serine at position 204 or a methionine at position 180 and a serine at position 204, are necessary to create a variant?

Claims 15, 19 and 29 recite the limitation "the discriminatory signal." There is insufficient antecedent basis for this limitation in the claim.

Claims 29 and 30 recite the limitation "oligonucleotides." There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1, 2, 3, 8, 9, 13, 14, 17 and 18 are rejected under 35 U.S.C. 102(a) as being anticipated by Bozdayi et al. For this rejection, it is assumed that claims 8 and 9 refer to a variant Hepatitis B virus.

Bozdayi et al. describes the isolation of nucleic acids (PCR products) from sera of patients infected with HBV. The nucleic acids have mutations that result in amino acid changes L528M and M552S. These amino acid changes correspond to positions L180M and M204S in the HBV reverse transcriptase domain.

Conclusion

Claims 3, 10, 16, and 20-28 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Allowable Subject Matter

Claims 4, 5 and 7 are free of the prior art and allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicole E. Kinsey, Ph.D. whose telephone number is (571) 272-9943. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Nicole E Kinsey, Ph.D.
Examiner
Art Unit 1648

Stacy B. Chen 2/20/07

STACY B. CHEN
PRIMARY EXAMINER